

II. BRIEF DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

The present invention, as defined by the claims, is directed generally to a system for ablating tissue. As shown by way of example in FIGS. 59 and 60, a system 298 in accordance with one embodiment of the invention includes a controller 300 and a probe 180 that may be inserted into the body. The probe includes an ablation element 176(1) which, in the exemplary embodiment, consists of a plurality of conductive regions E1 to E7 that form an energy emitting region 192.

The exemplary controller 300, which can be used to selectively switch the operation of the electrodes between unipolar and bipolar ablation modes, includes an input panel 302 and an **ON/OFF/MODE** toggle switch T_M . The toggle switch T_M allows the user turn the controller on and off and, if on, to select one of the unipolar and bipolar ablation modes. The exemplary controller 300 also includes a plurality of manually operable toggle switches T_{E1-E7} that can be used to selectively block transmission to **SOME OR ALL** of the respective conductive regions E1 to E7 to selectively form a variety of lesion patterns and lengths. [See the specification from, for example, page 53, line 31 to page 58, line 17 and FIGS. 59-66.] Some of these lesion patterns are formed when two conductive regions are separated by a non-conductive region. [See FIGS. 33-35.]

III. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

A. The Rejection

Claims 13, 16, 17, 19 and 20 have been rejected under 35 U.S.C. § 112, first paragraph, as purportedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, has possession of the invention. More specifically, the Office Action states that there is no support for “altering the length from a first non-zero length to a second non-zero length” and “an interface and a separate

control device.” The rejection under 35 U.S.C. § 112, first paragraph, is respectfully traversed. Reconsideration thereof is respectfully requested.

B. The Non-Zero Length Issue

As discussed in detail in the amendment filed January 30, 2001, the specification provides clear support for the “control means for varying the length of the region where transmission is allowed between a first non-zero length and a second non-zero length in response to the second input command” aspect of the combination defined by claim 13. In response to these arguments, the outstanding Office Action appears to incorrectly depict the respective functions of the exemplary toggle T_M and toggles T_{E1} to $E7$ described in the specification and their relationship to the elements of independent claim 13. [See pages 4 and 5 of the Office Action.]

With respect to the toggle T_M , and as clearly described in the specification, the toggle T_M is used to turn the controller 300 on and off and to select the mode of use (bipolar or unipolar) when on. Power is supplied in **unipolar** mode when the toggle T_M is in **position A**, **no power** is supplied when the toggle T_M is in **position B**, and power is supplied in **bipolar** mode when the toggle T_M is in **position C**. Again, the toggle T_M is used to determine whether or not the controller 300 is off (FIG. 62) or on and, if on, whether the power is supplied in unipolar mode (FIGS. 63 and 64) or bipolar mode (FIGS. 65 and 66).

Toggles T_{E1} to $E7$, on the other hand, are used for **INDIVIDUAL ELECTRODE CONTROL**. The toggles T_{E1} to $E7$ are individually coupled to the switches S_{E1} to $E7$, which control the flow of power to the respective conductive regions $E1$ to $E7$, by wires W_1 to W_7 . Each of the toggles T_{E1} to $E7$ may be **individually** placed in one of three positions. Power is supplied in **unipolar mode** to a conductive region E when the associated toggle T_E is in **position A**, no power is supplied to a conductive region E when the associated toggle T_E is in **position B**, and power is supplied in **bipolar mode** to a conductive region E when the associated toggle T_E is in **position C**.

With respect to unipolar ablation for example, and as described in the specification at page 59, lines 4-7, “[w]ith toggle T_M in Position A and **all toggles $T_{E1 \text{ to } E7}$ in their positions A, a continuous, unipolar lesion pattern results** ... like that shown in FIGS. 31 and 32.” In other words, the specification describes a situation where the controller 300 is set to unipolar mode (i.e. toggle T_M in Position A) and power is supplied to all of the conductive regions E1 to E7 (i.e. all toggles $T_{E1 \text{ to } E7}$ in their respective positions A).

The specification also states that “the physician can select to **electronically interrupt the flow of RF energy to one or more regions E1 to E7**” and that “**an interrupted, unipolar lesion pattern results** (like that shown in FIGS. 34 and 35).” [Page 59, lines 8-19.] Flow is selectively interrupted to regions E1 to E7 by selectively manipulating the toggles $T_{E1 \text{ to } E7}$. In other words, the specification describes a situation where the controller 300 is set to unipolar mode (i.e. toggle T_M in Position A) and power is supplied to less than all of the conductive regions E1 to E7 (i.e. some of the toggles $T_{E1 \text{ to } E7}$ in their respective positions B, and others in their respective positions A).

One of ordinary skill in the art would clearly understand that placing **less than all** of the toggles $T_{E1 \text{ to } E7}$ in their positions A is a “first input command” that will block transmission from a portion of the region defined by the conductive regions E1 to E7. It will also result in one or more lesions of a first non-zero length. [Note FIGS. 34 and 35.] One of ordinary skill in the art would also clearly understand that, for example, placing **all** of the toggles $T_{E1 \text{ to } E7}$ in their positions A is a “second input command” that will result in a lesion of a second non-zero length. [FIGS. 31 and 32.]

Turning to the discussion in the Office Action at page 4, line 12 to page 5, line 12, applicant respectfully submits that the majority of this discussion is moot in view of the explanation above. However, applicant does note that claim 13 is simply directed to a system that can operate in at least two different modes – one which produces a lesion of a first non-zero length and a second which produces a lesion of a second non-zero length. In the “shape and ablate situation” mentioned in the Office Action, the first lesion may be a first non-zero length and the second lesion may be a second non-zero length. Moreover, nothing in the claim in any way requires that the electrodes be either

“powered down” or not “powered down” in between the formation of two lesions, as apparently asserted in the Office Action.

In view of the foregoing, applicant again respectfully submits that even the most cursory review of Figures 31, 32, 34 and 35 and the above-quoted portions of the specification would have led a skilled artisan to understand that a lesion produced by all of the regions E1 to E7 will be one non-zero length, while a lesion produced by fewer than all of the regions will be another non-zero length (i.e. smaller). As such, the “non-zero length” portion of the rejection under 35 U.S.C. § 112, first paragraph, is improper should be withdrawn.

B. Interface and Controller Issue

Independent claim 13 calls for an “operator interface operable during an ablation procedure that receives at least first and second predetermined input commands” and “control means ...” Applicant respectfully submits that, with respect to the exemplary embodiment discussed above, the input panel 302 corresponds to the “operator interface” and the “switches $S_{E1 \text{ to } E7}$ ” correspond to the “control means.” As such, the “interface and controller” portion of the rejection under 35 U.S.C. § 112, first paragraph, is improper should also be withdrawn.

IV. PRIOR ART REJECTIONS

A. The Rejections

Claims 13, 16, 19 and 20 have been rejected under 35 U.S.C. § 102 as being anticipated by the Eggers '443 patent. Claim 17 has been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Eggers '443 and Avitall '297 patents. Claims 28, 30, 32, 33, 35, 36, 38, 39 and 41-46 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Eggers '443 and Desai '198 patents. Claim 40 has been rejected under 35 U.S.C. § 103 as being

unpatentable over the combined teachings of the Eggers '443, Desai '198 and Fogarty '769 patents. The rejections under 35 U.S.C. §§ 102 and 103 are respectfully traversed. Reconsideration thereof is respectfully requested.

B. The Cited References

As discussed in the amendment filed on January 30, 2001, the Eggers patent is directed to a system that may be used to selectively heat atheromatous (or stenotic) material within a blood vessel while limiting the amount of heat applied to blood and the blood vessel wall. [Column 4, lines 49-54.] The system includes a catheter 10 with an array of isolated electrodes 18 disposed on the catheter tip 12. The electrodes 18 are connected to a power source 32 that includes an operator interface with a voltage control knob 34, a temperature control knob 36, and what appears to be a single on-off switch that enables/disables power to all of the electrodes. The catheter tip 12 is provided with temperature sensors 48. The temperature sensors 48 are not specifically associated any particular electrodes 18. Rather, a few temperature sensors 48 are packed in with mass of electrodes 18. [Note Figure 3.] Alternatively, each electrode may function as a thermocouple so that the maximum temperature on the tip 12 may be determined. [Column 11, lines 43-54.]

In contrast to the claimed combinations, the Eggers power source 32 **does not** block transmission from (or disconnect power to) **some** of the electrodes during an ablation procedure **in response to a command** input into the operator interface. Rather, the power source 32 either (1) automatically blocks power to some of the electrodes 18 when those electrodes are transmitting power through a relatively low resistance path (column 3, lines 18-28 and column 6, line 57 to column 7, line 17) or (2) **automatically controls the “voltage, current, duty cycle, or the like”** when the sensed temperature is greater than the temperature set with control knob 36 (column 7, lines 58-68). Nothing in the Eggers patent even remotely suggest that the “voltage, current, duty cycle, or the like” supplied to the electrodes is varied on an electrode by electrode basis.

It is also noteworthy that Eggers blocks transmission to individual electrodes for one reason, and varies "voltage, current, duty cycle, or the like" to those where transmission is not blocked for another reason. More specifically, Eggers system determines whether an electrode is transmitting power to atheromatous material (which is desirable), or is transmitting power to blood or a blood vessel wall (which is undesirable), and then blocks transmission to those electrodes which are transmitting power to the blood or blood vessel wall. Next, for those electrodes that are transmitting power to atheromatous material, the Eggers system uses a temperature set point to maintain the atheromatous material at the desired temperature.

Accordingly, in contrast to the invention defined by independent claim 13, the Eggers patent fails to teach or suggest a combination of elements including, *inter alia*, "at least one energy transmitting electrode defining an energy transmitting region on the guide element" and "control means for electrically coupling the region to a source of tissue ablating energy, selectively electrically altering the energy transmitting characteristics of the region to block transmission from portion of the region while allowing transmission from another portion of the region in response to the first input command, and electrically varying the length of the region where transmission is allowed between a first non-zero length and a second non-zero length in response to the second input command."

The Eggers patent also fails to teach or suggest a combination of elements including, *inter alia*, "a plurality of longitudinally spaced electrodes" and "switching means for selectively disconnecting at least one of the electrodes within the plurality of longitudinally spaced electrodes from the source of tissue ablating energy in response to the first predetermined input command such that two electrodes are electrically connected to the source of tissue ablating energy and the at least one disconnected electrode is between the two connected electrodes," as called for in independent claim 28.

The Eggers patent also fails to teach or suggest a combination of elements including, *inter alia*, "at least first, second and third contiguous electrodes" and "a control device... operable in a first mode in response to the first input command to

simultaneously electronically couple the first, second and third electrodes to a source of tissue ablation energy ... and operable in a second mode in response to the second input command to block transmission from one of the first, second and third electrodes while simultaneously electronically coupling the other of the first, second and third electrodes to a source of tissue ablation energy,” as called for in independent claim 33.

The Avitall, Desai and Fogarty, which have been cited for their purported teachings of electrode structures, computer controlled switches, and other electrode structures, fail to remedy the above identified deficiencies in the Eggers patent.

C. The Remarks in the May 10, 2001 Office Action

The November 13, 2000 Office Action incorrectly asserted that a command input via the temperature control knob 36 “will cause the interruption of power to some of the electrodes and not others.” [November 13, 2000 Office Action at page 4.] In response applicant correctly noted that the Eggers patent clearly states that when the temperature measured at the tip 12 exceeds the temperature input with the control knob 36, the power supply 32 will automatically control the “voltage, current, duty cycle, or the like.” [Column 7, lines 58-68.] Again, nothing in the Eggers patent even remotely suggests that power will be **CUT OFF to some of the electrodes and not others in response to a TEMPERATURE measurement**. The Eggers system only controls the “voltage, current, duty cycle, or the like” supplied to the electrodes in response to temperature readings and, moreover, does not even vary “voltage, current, duty cycle, or the like” on an electrode by electrode basis.

Applicant also somewhat incorrectly argued that the Eggers patent does not disclose temperature sensing at each individual electrode. As noted on page 5 of the outstanding Office Action, the Eggers patent does in fact discuss a method of identifying the “maximum temperature at any location on the catheter tip.” [Column 11, lines 43-54.] The Eggers patent goes on to state that the maximum temperature information “can then be used in the feedback control loop as described above to assure an improved safe upper limit on the operating temperature.” [Id.] Thus, despite the fact that Eggers teaches

that the highest temperature amongst the electrodes may be identified (as opposed to merely measuring temperature at few sensors packed within the electrodes), nothing in the Eggers patent even remotely suggests that power will be ***CUT OFF to some of the electrodes and not others in response to the highest temperature reading.*** Again, the Eggers system only controls the “voltage, current, duty cycle, or the like” supplied to the electrodes in response to temperature readings and, moreover, does not even vary “voltage, current, duty cycle, or the like” on an electrode by electrode basis.

The outstanding Office Action, at pages 5 and 6, goes on to argue that the Eggers electrodes “are dynamically switched on and off dependent on local temperature.” As discussed in detail above, this is entirely incorrect. “Voltage, current, duty cycle, or the like” are varied to maintain temperature at a set temperature. Power is only “switched off” to electrodes are that are transmitting power through a resistance path that is indicative of blood or a blood vessel.

D. Conclusions

As the Eggers patent fails to teach or suggest each and every element of the inventions defined by independent claim 13, applicant respectfully submits that the rejection of claims 13, 16, 19 and 20 under 35 U.S.C. § 102 should be withdrawn.

As the combined teachings of the Eggers and Avitall patents fail to teach or suggest the combination defined by claim 17, applicant respectfully submits that claim 17 is patentable thereover and that the rejection under 35 U.S.C. § 103 should be withdrawn.

As the combined teachings of the Eggers and Desai patents fail to teach or suggest the respective combinations defined by independent claims 28 and 33, applicant respectfully submits that claims 28, 30, 32, 33, 35, 36, 38, 39 and 41-46 are patentable thereover and that the rejection under 35 U.S.C. § 103 should be withdrawn.

As the combined teachings of the Eggers, Desai and Fogarty patents fail to teach or suggest the combination defined by independent claim 33, applicant respectfully submits that claim 40 is patentable thereover and that the rejection under 35 U.S.C. § 103 should be withdrawn.

V. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application patentably distinguish over the cited and applied references and are in condition for allowance. Reexamination and reconsideration of the application are respectfully requested. Allowance of the claims at an early date is courteously solicited.

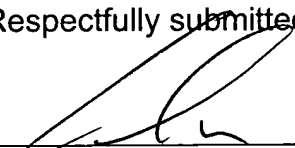
If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

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Respectfully submitted,



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